IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

RYAN VANDERSTELT;

LAURA GARDNER;

RACHELLE VILLEGAS;

TIFFANY FANT;

TODD MERZ;

DAWN VAN RIPER;

PETER BULSON;

JOHN GATELEY;

SANDRA HAND;

MELISSA MOORE;

KENT BALTZER;

on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

JOSEPH R. BIDEN in his official capacity as President of the United States;

UNITED STATES OF AMERICA;

SAFER FEDERAL WORKFORCE TASK FORCE;

UNITED STATES OFFICE OF PERSONNEL MANAGEMENT;

KIRAN AHUJA in her official capacity as Director of the Office of Personnel

CIVIL CASE NO. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE, AND OTHER RELIEF

JURY TRIAL DEMANDED

Management and as Co-Chair of the Safer Federal Workforce Task Force;

OFFICE OF MANAGEMENT AND BUDGET;

SHALANDA YOUNG in her official capacity as Acting Director of the Office of Management and Budget and as a Member of the Safer Federal Workforce Task Force;

GENERAL SERVICES ADMINISTRATION;

ROBIN CARNAHAN in her official capacity as Administrator of the General Services Administration and as Co-Chair of the Safer Federal Workforce Task Force;

JEFFREY ZIENTS in his official capacity as Co-Chair of the Safer Federal Workforce Task Force and COVID-19 Response Coordinator;

L. ERIC PATTERSON in his official capacity as Director of the Federal Protective Service and as a Member of the Safer Federal Workforce Task Force;

JAMES M. MURRAY in his official capacity as Director of the United States Secret Service and as a Member of the Safer Federal Workforce Task Force;

DEANNE CRISWELL in her official capacity as Administrator of the Federal Emergency Management Agency and as a Member of the Safer Federal Workforce Task Force;

ROCHELLE WALENSKY in her official capacity as Director of the Centers for Disease Control and Prevention and as a Member of the Safer Federal Workforce Task Force;

FEDERAL ACQUISITION REGULATORY COUNCIL;

LESLEY A. FIELD in her official capacity as Acting Administrator for Federal Procurement, Office of Management and Budget;

JEFFREY A. KOSES in his official capacity as Senior Procurement Executive & Deputy Chief Acquisition Officer, General Services Administration;

JOHN M. TENAGLIA in his official capacity as Principal Director of Defense Pricing and Contracting, Department of Defense;

KARLA S. JACKSON in her official capacity as Assistant Administrator for Procurement, National Aeronautics and Space Administration;

Defendants.

Plaintiffs and those similarly situated, by and through their attorneys at the New Civil Liberties Alliance ("NCLA"), hereby complain and allege the following:

INTRODUCTORY STATEMENT

After announcing that his "patience is wearing thin" with Americans who elect not to receive a COVID-19 vaccine,[1] President Biden signed an unlawful executive order to compel millions of Americans who work for government contractors, even if not performing contract work, to take a COVID-19 vaccine. Exec. Order 14042, *Ensuring Adequate COVID Safety Protocols for Federal Contractors*, 86 Fed. Reg. 50,985 (Sept. 9, 2021). A vague and confusing set of instructions with shifting deadlines and justifications followed, including, *inter alia*:

[1] The White House, *Remarks by President Biden on Fighting the COVID-19 Pandemic* (Sep. 9, 2021), available at https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ (last visited Jan. 3, 2022).

- Mandates, deceptively framed as guidance, that workers of federal contractors and subcontractors must get vaccinated by December 8, 2021, which was pushed to a new deadline of January 18, 2022, in recognition of workforce and supply chain disruptions that the mandate would cause—and still will.
- A determination published in the Federal Register by the Office of Management and Budget ("OMB") approving the above guidance, which was rescinded and superseded by revised and expanded justifications.
- A memorandum issued by the Federal Acquisition Regulatory Council ("FAR Council Memo") advising executive agencies on how to revise contracting documents to effectuate the vaccine requirements in the absence of formal regulations, which had not yet been issued.

Together, these pronouncements impose the "Federal Contractor Vaccine Mandate," which is intended to and has the effect of forcing virtually everyone who works for a federal contractor or subcontractor—even if they do not work in connection with a federal contract—to receive an emergency-use-only vaccine or else lose their jobs. This unprecedented coercive tactic compels many Americans to receive a vaccine they do not need or want, erodes their personal liberty, and inflicts irreparable harm upon millions of workers all without lawful basis. The mandate is a blatant attempt to end-run the federal government's lack of police power, and it thereby constitutes *ultra vires* action and an abuse of the federal procurement statute. Pandemic notwithstanding, "our system does not permit agencies to act unlawfully even in the pursuit of desirable ends." *Ala. Ass'n of Realtors v. Dep't of Health and Human Servs*., 141 S. Ct. 2485, 2490 (2021) (per curiam). The Plaintiffs therefore seek judicial relief from the President's unlawful and unconstitutional vaccine mandate.

PARTIES

1. Plaintiffs are all individuals who work for federal contractors subject to the Federal Contractor Vaccine Mandate. They are all required by their federal contractor employers to receive a COVID-19 vaccine, even though most Plaintiffs are either naturally immune due to recovering from a prior COVID-19 infection, working remotely on a full-time basis, or both.

2. Plaintiff Ryan Vanderstelt is a resident of White Cloud, Michigan, and is employed as a Medical Review Specialist by BlueCross/BlueShield of Michigan, which is a federal contractor. Mr. Vanderstelt has natural immunity to COVID-19 due to recovering from a prior infection. In an effort to comply with the Federal Contractor Vaccine Mandate, BlueCross/BlueShield is forcing Mr. Vanderstelt to be fully vaccinated and submit proof of vaccination, even though he is naturally immune. If Mr. Vanderstelt does not comply with the Federal Contractor Vaccine Mandate, his employer will be forced to terminate him.

3. Plaintiff Laura Gardner is a resident of Sand Lake, Michigan, and is employed as a Customer Service Specialist by BlueCross/BlueShield of Michigan, which is a federal contractor. Ms. Gardner has natural immunity to COVID-19 due to recovering from a prior infection. In an effort to comply with the Federal Contractor Vaccine Mandate, BlueCross/BlueShield is forcing Ms. Gardner to be fully vaccinated and submit proof of vaccination, even though she is naturally immune. If Ms. Gardner does not comply with the Federal Contractor Vaccine Mandate, her employer will be forced to terminate her.

4. Plaintiff Rachelle Villegas is a resident of Allendale, Michigan, and is employed as a Trainer II by BlueCross/BlueShield of Michigan, which is a federal contractor. Ms. Villegas has natural immunity to COVID-19 due to recovering from a prior infection. In an effort to comply with the Federal Contractor Vaccine Mandate, BlueCross/BlueShield is forcing Ms. Villegas to be

fully vaccinated and submit proof of vaccination, even though she is naturally immune. If Ms. Villegas does not comply with the Federal Contractor Vaccine Mandate, her employer will be forced to terminate her.

5. Plaintiff Tiffany Fant is a resident of Grand Rapids, Michigan, and is employed as a Claims Liaison by BlueCross/BlueShield of Michigan, which is a federal contractor. Ms. Fant has natural immunity to COVID-19 due to recovering from a prior infection. In an effort to comply with the Federal Contractor Vaccine Mandate, BlueCross/BlueShield is forcing Ms. Fant to be fully vaccinated and submit proof of vaccination, even though she is naturally immune. If Ms. Fant does not comply with the Federal Contractor Vaccine Mandate, her employer will be forced to terminate her.

6. Plaintiff Todd Merz is a resident of Berkley, Michigan, and is employed as a Rating and Underwriting Consultant by BlueCross/BlueShield of Michigan, which is a federal contractor. Mr. Merz works remotely on a full-time basis and has natural immunity to COVID-19 due to recovering from a prior infection. In an effort to comply with the Federal Contractor Vaccine Mandate, BlueCross/BlueShield is forcing Mr. Merz to be fully vaccinated and submit proof of vaccination, even though he works remotely and is naturally immune. If Mr. Merz does not comply with the Federal Contractor Vaccine Mandate, his employer will be forced to terminate him.

7. Plaintiff Dawn Van Riper is a resident of Novi, Michigan, and is employed as an IT Solution Specialist by Ford Motor Company, which is a federal contractor. Ms. Van Riper has natural immunity to COVID-19 due to recovering from a prior infection. In an effort to comply with the Federal Contractor Vaccine Mandate, Ford is forcing Ms. Van Riper to be fully vaccinated and submit proof of vaccination, even though she is naturally immune. If Ms. Van Riper does not

comply with the Federal Contractor Vaccine Mandate, Ford will be forced to place her on unpaid leave, with further disciplinary action up to and including termination.

8. Plaintiff Sandra Hand is a resident of Fulton, Maryland, and works as a System Manager II for Leidos, Inc., which is a federal contractor. Ms. Hand has natural immunity to COVID-19 due to recovering from a prior infection. In an effort to comply with the Federal Contractor Vaccine Mandate, Leidos is requiring Ms. Hand to be fully vaccinated and submit proof of vaccination, even though she is naturally immune. If Ms. Hand does not comply with the Federal Contractor Vaccine Mandate and upload a proof of vaccination, her employer will be forced to place her on unpaid leave, with further disciplinary action up to and including termination to follow.

9. Plaintiff Melissa Moore is a resident of Moon Township, Pennsylvania, and is self-employed as a provider of captioning services for deaf audiences. She works remotely from her home office on a full-time basis and has natural immunity from a prior COVID-19 infection. Ms. Moore is a subcontractor for federal contractors and is thus covered by the Federal Contractor Vaccine Mandate. The Federal Contractor Vaccine Mandate requires Ms. Moore to be fully vaccinated to continue working as a federal subcontractor, even though she has natural immunity and works remotely. If Ms. Moore does not comply with the Federal Contractor Vaccine Mandate, her federal contractor customers will be forced to terminate their business relationship with her.

10. Plaintiff Peter Bulson is a resident of Redondo Beach, California, and works as an Account Executive, Corporate Investigations for Reuters, which is a federal contractor. He works remotely from his home office on a full-time basis and has natural immunity from a prior COVID-19 infection. In an effort to comply with the Federal Contractor Vaccine Mandate, Reuters is requiring Mr. Bulson to be fully vaccinated and submit proof of vaccination, even though he is

naturally immune and works remotely. If Mr. Bulson does not comply with the Federal Contractor Vaccine Mandate and upload his proof of vaccination, his employer will be forced to terminate him.

11. Plaintiff Jon Gateley is a resident of St. Paul, Minnesota, and works as a Manager II at Okta, which is a federal contractor. In an effort to comply with the Federal Contractor Vaccine Mandate, Okta is requiring Mr. Gateley to be fully vaccinated and submit proof of vaccination, even though he works remotely from home on a full-time basis. If Mr. Gateley does not comply with the Federal Contractor Vaccine Mandate and submit his proof of vaccination, his employer will be forced to place him on unpaid leave, followed by termination if he still does not comply.

12. Plaintiff Kent Baltzer is a resident of Kernersville, North Carolina, and works for a demolition company that does business as a federal contractor and subcontractor. In an effort to comply with the Federal Contractor Vaccine Mandate, Mr. Baltzer's employer is requiring him to submit proof of vaccination. If Mr. Baltzer does not comply with the Federal Contractor Vaccine Mandate and submit his proof of vaccination, his employer will be forced to terminate him.

DEFENDANTS

13. Defendants are the United States of America, the President of the United States, appointed officials of the United States government, and United States governmental agencies responsible for the issuance and implementation of the Federal Contractor Vaccine Mandate.

14. Defendant Joseph R. Biden, sued in his official capacity, is the President of the United States who, on September 9, 2021, said that his patience is wearing thin and signed Executive Order 14042. 86 Fed. Reg. 50,985 (Sept. 9, 2021).

15. Defendant Safer Federal Workforce Task Force ("Task Force") was established pursuant to President Biden's Executive Order 13991. 86 Fed. Reg. 7045, 7046 (Jan. 25, 2021).

Three co-chairs oversee the Task Force, including: (1) the Director of the Office of Personnel Management; (2) the Administrator of the General Services Administration; and (3) the COVID-19 Response Coordinator. *Id.* The Director of the Office of Personnel Management is also a member of the Task Force. *Id.*

16. Defendant Office of Personnel Management is an agency of the United States government. Defendant Office of Personnel Management Director, Kiran Ahuja, sued in her official capacity, is a co-chair and member of the Task Force and represents the federal agency responsible for managing human resources for civil service of the federal government.

17. Defendant Office of Management and Budget ("OMB") is an agency of the United States government, specifically, within the Executive Office of the President, and issued the determinations finding that the Task Force's Guidance issued on September 24, 2021, and updated on November 10, 2021, will improve "economy and efficiency by reducing absenteeism and decreasing labor costs for contractors and subcontractors working on or in connection with a Federal Government contract." *See Determination of the Promotion of Economy and Efficiency in Federal Contracting Pursuant to Executive Order No. 14042* ("OMB Determination"), 86 Fed. Reg. 53,691 (Sept. 28, 2021); *Determination of the Acting OMB Director Regarding the Revised Safer Federal Workforce Task Force Guidance for Federal Contractors and the Revised Economy & Efficiency Analysis*, (Revised Determination), 86 FR 63418 (Nov. 16, 2022).

18. Defendant Shalanda Young is the Acting Director of the Office of Management and Budget and a member of the Task Force. She represents the federal agency with delegated authority to publish determinations relevant to Executive Order 14042 to the Federal Register. She is sued in her official capacity.

19. Defendant General Services Administration routinely contracts with entities to supply goods and services for federal agencies.

20. Defendant Administrator of General Services, Robin Carnahan, sued in her official capacity, is a co-chair and member of the Task Force and represents the federal agency responsible for managing and supporting the basic functioning of federal agencies.

21. Defendant COVID-19 Response Coordinator, Jeffrey Zients, sued in his official capacity, is a co-chair and member of the Task Force and is the Biden Administration's COVID-19 Response Coordinator.

22. Defendant Director of the Federal Protective Service, L. Eric Patterson, sued in his official capacity, is a member of the Task Force.

23. Defendant Director of the United States Secret Service, James M. Murray, sued in his official capacity, is a member of the Task Force.

24. Defendant Director of the Federal Emergency Management Agency, Deanne Criswell, sued in her official capacity, is a member of the Task Force.

25. Defendant Director of the Centers for Disease Control and Prevention, Rochelle Walensky, sued in her official capacity, is a member of the Task Force.

26. Defendant Federal Acquisition Regulatory Council ("FAR Council") is responsible for "manag[ing], coordinat[ing], control[ling], and monitor[ing] the maintenance of, issuance of, and changes in, the Federal Acquisition Regulation." 41 U.S.C. § 1303(d).

27. Defendant Lesley A. Field, sued in her official capacity, is a member of the FAR Council by virtue of her role as the Acting Administrator for Federal Procurement of OMB.

28. Defendant Jeffrey A. Koses, sued in his official capacity, is a member of the FAR Council by virtue of his role as the Senior Procurement Executive & Deputy Chief Acquisition Officer of the General Services Administration.

29. Defendant John M. Tenaglia, sued in his official capacity, is a member of the FAR Council by virtue of his role as the Principal Director of Defense Pricing and Contracting of the Department of Defense.

30. Defendant Karla S. Jackson, sued in her official capacity, is a member of the FAR Council by virtue of her role as the Assistant Administrator for Procurement of NASA.

JURISDICTION AND VENUE

31. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1346, and 1361, as well as under 5 U.S.C §§ 702-703.

32. The Court is authorized to award the requested declaratory and injunctive relief under 5 U.S.C. §§ 702 and 706, 28 U.S.C. § 1361, and 28 U.S.C. §§ 2201-02, the Constitution, and the Court's equitable powers.

33. Venue is proper within this District pursuant to 28 U.S.C. § 1391. Defendants are United States agencies or officers sued in their official capacities. Plaintiffs Vanderstelt, Gardner, Villegas, and Fant reside in this judicial district.

STATEMENT OF FACTS

I. RELEVANT PROCUREMENT LAW

34. Congress enacted the Federal Property and Administrative Services Act ("Procurement Act") of 1949 "to provide the Federal Government with an economical and efficient system for" procurement. 40 U.S.C. § 101. The Act permits the President to "prescribe policies and directives that the President considers necessary to carry out" this purpose. *Id.* § 121(a).

Congress did not empower the President to issue regulations with the force or effect of law, as it authorized the General Services Administrator to do. *Compare id*. at § 121(a) ("prescribe policies and directives"), with *id.* at § 121(c) ("prescribe regulations"); *see Sosa v. Alvarez-Machain,* 542 U.S. 692 711 n.9 (2004) ("[W]hen the legislature uses certain language in one part of the statute and different language in another, … different meanings were intended.").

35. Presidential policies prescribed under the Procurement Act, and regulations enacted pursuant to them, are valid only if there is a "nexus between the regulations and some delegation of requisite legislative authority by Congress," which allows "the reviewing court [to] reasonably be able to conclude that the grant of authority contemplates the regulations issued." *Chrysler Corp. v. Brown*, 441 U.S. 281, 304, 308 (1979). Such a nexus does not exist when the policy in question is "too attenuated to allow a reviewing court to find the requisite connection between procurement cost and social objectives." *Liberty Mut. Ins. Co. v. Friedman*, 639 F.2 164, 171 (4th Cir. 1981). Nor does a nexus exist when such policy governs individuals who have "no direct connection to federal procurement." *Id.*

36. In 1979, to ensure greater consistency and coordination across federal agencies, Congress directed the Office of Federal Procurement Policy—part of the OMB—to "issue policy directives … for the purpose of promoting the development and implementation of [a] uniform procurement system," with concurrence of the OMB Director. *See* Office of Federal Procurement Policy Amendments of 1979, Pub. L. No. 96-83, § 4(e), 93 Stat. 650. In 1983, the Administrator of the Office of Federal Procurement Policy, the Department of Defense, General Services Administration, and NASA jointly promulgated the first version of the Federal Acquisition Regulation ("FAR"), *see* 48 Fed. Reg. 32,102, which is a set of policies and procedures that governs the drafting and procurement processes for contractors of all executive agencies, *see* U.S.

Gen. Serv. Adm. *Federal Acquisition Regulation* https://www.gsa.gov/policy-regulations/regulations/federal-acquisition-regulation-far (last visited Jan. 3, 2022).

37. In 1984, Congress enacted the Competition in Contracting Act ("CICA"), which mandates that federal agencies "shall obtain full and open competition through the use of competitive procedures" in their procurement activities unless otherwise authorized by law. 10 U.S.C. § 2304(a)(1)(A) (procurements of defense agencies); 41 U.S.C. § 253(a)(1)(A) (procurements of civilian agencies). A "full and open competition" means that "all responsible sources are permitted to submit sealed bids or competitive proposals on the procurement." 41 U.S.C. § 403(6). An "agency must follow the congressionally designed procedures" if it seeks to deviate from full and open competition. *Nat'l Gov't Servs., Inc. v. United States*, 923 F.3d 977, 990 (Fed. Cir. 2019).

38. In 1988, Congress established the FAR Council—which consists of the heads of the Office of Procurement Policy, Department of Defense, NASA, and GSA—"to assist in the direction and coordination of Government-wide procurement policy and Government-wide procurement regulatory activities in the Federal government." 41 U.S.C. § 1302(a), (b). Subject to limited exceptions, the FAR Council has exclusive authority to issue "a single Government-wide procurement regulation." *Id.* § 1302(a)(1). No other agency is authorized to issue government-wide procurement regulations. *Id.* § 1302(a)(2).

39. Under the Office of Federal Procurement Policy Act, "a procurement policy, regulation, procedure or form" that "relates to the expenditure of appropriated funds" and "has significant cost or administrative impact on contractors or offerors" "may not take effect until 60 days after it is published for comment in the Federal Register." 41 U.S.C. § 1707(a). This notice-

and-comment requirement may be waived only if "urgent and compelling circumstances make compliance with the requirements impracticable." *Id.* § 1707(d).

II. BACKGROUND OF THE CORONAVIRUS PANDEMIC AND COVID-19 VACCINES

40. The novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, is contagious and spreads mainly from person to person, including through the air.

41. The coronavirus presents a significant risk primarily to individuals aged 70 or older and those with comorbidities such as obesity and diabetes. Bhattacharya and Kulldorff Joint Decl. ¶¶ 10-14 ("Joint Decl.") (Attachment A). *See* Smiriti Mallapaty, *The Coronavirus Is Most Deadly If You Are Older and Male*, NATURE (Aug. 28, 2020), *available at* https://www.nature.com/articles/d41586-020-02483-2 (last visited Jan. 3, 2022) (individuals 50 years or under face a negligible threat of a severe medical outcome from a coronavirus infection, akin to the types of risk that most people take in everyday life, such as driving a car).

42. A meta-analysis published by the WHO concluded that the survival rate for COVID-19 patients under 70 years of age is 99.95%. *Id.* ¶ 12. CDC estimates that the survival rate for young adults between 20 and 49 is 99.95%, and for people ages 50-64 is 99.4%. *Id.* A seroprevalence study of COVID-19 in Geneva, Switzerland, reached a similar conclusion, estimating a survival rate of approximately 99.4% for patients between 50 and 64 years old, and 99.95% for patients between 20 and 49. *Id.* at ¶ 13.

43. Last winter, FDA approved three vaccines pursuant to the federal Emergency Use Authorization ("EUA") statute, 21 U.S.C. § 360bbb-3.

a. FDA issued an EUA for Pfizer's BioNTech Vaccine on December 11, 2020.

b. Just one week later, FDA issued an EUA for the Moderna Vaccine.

c. FDA issued its most recent EUA, for the Janssen Vaccine, on February 27, 2021.

44. An EUA is not a full FDA license and merely represents the FDA's conclusion that a product may be effective in a public health emergency where there is no "adequate, approved, and available alternative." *Id.* § 360bbb-3(a)-(c). EUA drugs may not be administered unless the patient is informed "of the option to accept or refuse administration of the product." *Id.* § 360bbb-3(e)(1)(A)(ii)(III).

45. On August 23, 2021, Pfizer's Comirnaty Vaccine received full FDA approval. In a letter to Pfizer, FDA states that "the Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) have the same formulation. The products are *legally distinct with certain differences* that do not impact safety or effectiveness." (Emphasis added). FDA, "Letter to Pfizer, Inc." (October 29, 2021), *available at* https://www.fda.gov/media/150386/download (last visited Jan. 3, 2022).

46. Information regarding the differences between the BioNTech Vaccine and the Comirnaty Vaccine is not readily available. Generally speaking, certain drugs that the public believes are identical, generic versions of brand name drugs for instance, do not need to be formulaically identical in actuality. FDA, "Generic Drugs: questions & Answers," *available at* https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q5 (last visited Jan. 3, 2022). An analysis of the ingredients in the two confirms they are not, in fact, identical.

47. The EUA status of the vaccines that are available at present in the United States means that FDA has not yet fully approved them but nonetheless permits their conditional use due to exigent circumstances. A federal court has concluded that Pfizer's Comirnaty and BioNTech vaccines are not interchangeable "as a legal matter," and that the prohibition against forcing military servicemembers to take EUA vaccines under 10 U.S.C. § 1107a applies to the EUA BioNTech vaccine. *Doe v. Austin*, Case No. 3:21-cv-01211, 2021 WL 5816632, at *6 n.9, (N.D.

Fl. Nov. 12, 2021) ("[T]he DOD cannot rely on the FDA to find that the two drugs are legally identical for § 1107a purposes.").

48. "Excipients" (inactive ingredients) "may affect the safety and effectiveness of drugs products." *Id.* at *3 fn. 5 (*citing United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 (1983) (two products with the same active ingredients were *not* the same, given that district court had determined that the unlicensed drug was "less safe and effective.")).

49. The FDA's definition of interchangeable means that a drug can be substituted for a licensed "reference product without the intervention of the healthcare provider who prescribed the reference product … because it is 'biosimilar' and 'can be expected to produce the same clinical result as the reference product." *Austin*, 2021 WL 5816632, at *9 n.13. In *Austin*, the court explained that even though a name-brand drug might be deemed "interchangeable" by the generic version by the FDA, "because healthcare providers administer COVID-19 vaccines directly, there is no scenario in which a patient would receive an EUA vaccine as a substitute to Comirnaty without his healthcare provider's intervention or approval." *Id.* at *9 fn. 13.

50. The standard for EUA review and approval is lower than that required for full FDA approval.

51. Typically, vaccine development includes six stages: (1) exploratory; (2) preclinical (animal testing); (3) clinical (human trials); (4) regulatory review and approval; (5) manufacturing; and (6) quality control. *See* CDC, *Vaccine Testing and the Approval Process* (May 1, 2014), *available at* https://bit.ly/3rGkG2s (last visited Jan. 3, 2022).

52. The third phase generally takes place over years, because it can take that long for a new vaccine's side effects to manifest. *Id.*

53. This phase must be followed by a period of regulatory review and approval, during which data and outcomes are peer-reviewed and evaluated by FDA. *Id.*

54. Finally, to achieve full approval, the manufacturer must demonstrate that it can produce the vaccine under conditions that assure adequate quality control.

55. FDA must then determine, based on "substantial evidence," that the medical product is effective and that the benefits outweigh its risks when used in accordance with the approved labeling. *See* CDC, *Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19* (Oct. 22, 2020), https://www.fda.gov/consumers/consumer-updates/understanding-regulatory-terminology-potential-preventions-and-treatments-covid-19 (last visited Jan. 3, 2022).

56. In contrast to this rigorous, six-step approval process that includes long-term data review, FDA grants EUAs in emergencies to "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic." FDA, *Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), *available at* bit.ly/3x8wImn (last visited Jan. 3, 2022).

57. EUAs allow FDA to make a product available to the public based on the best available data, without waiting for all the evidence needed for full approval. *See id.*

58. The EUA statute lays out the: "Appropriate conditions designed to ensure that individuals to whom the product is administered are informed." This means they must be told:

> that the Secretary has authorized the emergency use of the product; of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

21 U.S.C. § 360bbb-3(e)(1)(A)(i).

59. Studies of immunizations outside of clinical-trial settings began in December 2020, following the first EUA for a COVID vaccine.

60. None of the precise EUA vaccines approved for use in the United States has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. Recent research indicates that vaccination presents a heightened risk of adverse side effects—including serious ones—to those who have previously contracted and recovered from COVID-19. Joint Decl. ¶ 28.

61. The heightened risk of adverse effects results from "preexisting immunity to SARS-Cov-2 [that] may trigger unexpectedly intense, albeit relatively rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals." Angeli *et al.*, *SARS-CoV-2 Vaccines: Lights and Shadows*, 88 EUR. J. INTERNAL MED. 1, 8 (2021).

62. Because vaccines authorized under the EUA statute have not been fully approved by the FDA, informed and voluntary consent is required for their use. *See John Doe No. 1 v. Rumsfeld*, No. Civ. A. 03-707(EGS), 2005 WL 1124589, *1 (D.D.C. Apr. 6, 2005) (allowing use of anthrax vaccine pursuant to EUA "on a *voluntary* basis"). *See also* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).

63. Congress has explicitly authorized the President to waive the informed-and-voluntary-consent requirement to taking "a product authorized for emergency use under … the Federal Food, Drug, and Cosmetic Act [as] to members of the armed forces … only if the President determines, in writing, that complying with such requirement is not in the interest of national security." 10 U.S.C. § 1107a(a)(1). Congress has not authorized the President to waive the informed-and-voluntary-consent requirement for taking EUA products as to civilians, including civilian employees of federal contractors.

III. BACKGROUND OF THE FEDERAL CONTRACTOR VACCINE MANDATE

64. On January 20, 2021, President Biden issued Executive Order 13991 (86 Fed. Reg. 7,045), which established the Safer Federal Workforce Task Force ("Task Force") and charged it with "provid[ing] ongoing guidance to heads of agencies on the operation of the Federal Government, the safety of its employees, and the continuity of Government functions during the COVID-19 pandemic." *Id.* The Executive Order also requires that the General Services Administration "provide funding and administrative support for" the Task Force. *Id.* Three co-chairs oversee the Task Force: (1) the Director of the Office of Personnel Management, Defendant Ahuja; (2) the Administrator of the General Services Administration, Defendant Carnahan; and (3) the COVID-19 Response Coordinator, Defendant Zients. Defendants Young, Patterson, Murray, Criswell, Walensky are also members of the Task Force.

65. The Biden Administration initially made clear that mandatory vaccination is "not the role of the federal government." The White House, Press Briefing by Jen Psaki, July 23, 2021, https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/23/press-briefing-by-press-secretary-jen-psaki-july-23-2021/ (last visited Jan. 3, 2022). On September 9, 2021, however, President Biden changed his position, declaring that his "patience is wearing thin" and expressing "anger at those who haven't gotten vaccinated," without distinguishing those unvaccinated who have naturally acquired immunity. The White House, Remarks by President Biden on Fighting the COVID-19 Pandemic, Sep. 9, 2021, available at https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ (last visited Jan. 3, 2022). He announced three new administrative actions aimed at coercing a total of 100 million Americans to receive a COVID-19 vaccine. *Id.*[2]

[2] The President estimates the combined initiatives would affect 100 million Americans.

66. *First*, he announced the Occupational Safety and Health Administration (OSHA) would develop an emergency temporary standard mandating private employers with 100 or more employees to require their employees to become fully vaccinated, submit to routine testing, or be terminated. *Id.* On November 5, 2021, OSHA issued such an emergency temporary standard ("OSHA Mandate"), which the Fifth Circuit enjoined nationwide on November 12, 2021, as likely to be deemed unconstitutional and unlawful. *See BST Holdings, LLC v. OSHA*, 17 F.4th 604 (5th Cir. 2021). The Sixth Circuit lifted the Fifth Circuit's injunction, *In re: MCP No. 165*, OSHA, --- F.4th --- 2021 WL 5989357 (6th Cir. Dec. 17, 2021), and the issue is now being argued before the Supreme Court.

67. *Second*, the President announced that the federal government would mandate vaccines for employees of healthcare facilities that accept Medicare and Medicaid. *Id.* The Centers for Medicare and Medicaid Services ("CMS") issued an interim rule imposing such a mandate on November 5, 2021. *Medicare and Medicaid Program; Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61,555 (Nov. 5, 2021). On November 30, 2021, the Western District of Louisiana issued a nationwide injunction against this CMS mandate. *See Louisiana v. Becerra*, 2021 WL 5609846 (W.D. La. Nov. 30, 2021). The Fifth Circuit upheld the injunction but limited its scope to the 14 States that were party to the lawsuit. *Louisiana v. Becerra*, --- 4th ---, 2021 WL 5913302 (5th Cir. Dec. 17, 2021)*; see also Missouri v. Biden*, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021) (enjoining CMS mandate in Missouri and nine other states). The issue is now being argued before the Supreme Court.

68. *Third*, and most relevant in this case, the President announced that he would issue executive orders requiring all employees of the executive branch, as well as those working for federal contractors, to be vaccinated. The Federal Contractor Vaccine Mandate has been enjoined

by the United States District Courts for the Eastern District of Kentucky and Southern District of Georgia. *Kentucky v. Biden*, 2021 WL 5587446, at *14 (E.D. Ky. Nov. 30, 2021); *Georgia v. Biden*, 2021 WL 5779939, at *12 (S.D. Ga. Dec. 7, 2021). The Eleventh Circuit denied the government's motion to stay the nationwide injunction issued by the Southern District of Georgia "because the government has not established … that it will be irreparably injured absent a stay." *Georgia v. Biden*, No. 21-014269-F (11th Cir. Dec. 20, 2021).

A. The Federal Contractor Executive Order

69. On September 9, 2021, the President issued Executive Order 14042, which purports to rely on the President's authority under the Procurement Act to "promote[] economy and efficiency in Federal procurement by ensuring that the parties that contract with the Federal Government provide adequate COVID-19 safeguards to their workers." 86 Fed. Reg. 50,985. "[W]orkers employed by federal contractors" comprise "approximately one-fifth of the entire U.S. labor force," which totals about 32 million workers. U.S. Dep't of Labor, *History of Executive Order 11246*, https://www.dol.gov/agencies/ofccp/executive-order-11246/regulations (last visited Jan. 3, 2022).

70. Executive Order 14042 directs the Task Force to develop guidance for the federal contractor vaccine requirement and requires the OMB Director to publish a determination in the Federal Register as to "whether such Guidance will promote economy and efficiency in Federal contracting if adhered to by Government contractors and subcontractors." *Id.*

71. Executive Order 14042 further directs executive-branch agencies to ensure that "contracts and contract-like instruments [covered by the executive order] … include a clause [that specifies] that the contractor or subcontractor shall, for the duration of the contract, comply with

all guidance for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force," subject to approval by the OMB Director.

72. Executive Order 14042 also instructs the FAR Council to "amend the Federal Acquisition Regulation to provide for inclusion in Federal procurement solicitations and contracts subject to this order." The contract clause discussed above further instructs agencies to seek to implement the contract clause in contracts not covered by the FAR. *Id.* at 50,986.

73. Executive Order 14042 applies to new contracts, contract-like instruments, new solicitations for contracts or contract-like instruments, and extensions or renewals of contracts or contract-like instruments if the extension or renewal occurred on or after October 15, 2021. *Id.* at 50,987.

74. The Executive Order also authorized the Task Force to update guidance on a continuing basis, subject to re-approval by the OMB Director. 86 Fed. Reg. at 50,985 (noting the "contractor or subcontractor shall, for the duration of the contract, comply with all guidance for contractor or subcontractor workplace locations published by" the Task Force).

B. **The Task Force Guidance**

75. On September 24, 2021, the Task Force issued guidance that requires all "covered contractor employees" to be fully vaccinated by December 8, 2021. Safer Federal Workforce Task Force, COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors (Sep. 24, 2021) ("Task Force Guidance") (Attachment B).

76. The term "covered contractor employees," "includes employees of covered contractors who are not themselves working on or in connection with a covered contract." Task Force Guidance at 3-4.

77. In a lengthy Q&A Section, which the Task Force continues to update, the Task Force Guidance makes clear that covered contractor employees who have natural immunity conferred through prior COVID-19 infection must still be fully vaccinated. *Id.* at 10.

78. The Q&A Section of the Task Force Guidance also makes clear that employees who work exclusively from home or remotely are subject to the same stringent vaccination requirement as those who work in physical proximity to other employees. *Id.*

79. The Q&A Section further states that prime contractors are responsible for ensuring that subcontractors are adhering to the mandate. *Id.* at 13.

80. The Task Force Guidance requires the FAR Council to conduct rulemaking to amendment the FAR and develop a contract clause that agencies must use to impose the Federal Contractor Vaccine Mandate. *Id.* at 12. Agencies must use the Federal Contractor Vaccine Mandate contract clause in solicitations after October 15, 2021.[3]

81. The Task Force Guidance purports to supersede legal requirements in states or localities that prohibit vaccine mandates. *Id.* at 13.

82. Employees are considered fully vaccinated "if they have received COVID-19 vaccine currently approved or authorized for emergency use by the U.S. Food and Drug Administration." These are the Pfizer-BioNTech, Moderna, and Johnson & Johnson/Janssen vaccines—the fully approved Comirnaty vaccine is not listed as an option. Employees are also

[3] The Task Force Guidance imposes a deadline of November 14, 2021, after which awarded contracts must include that contractual clause. For contracts entered into between October 15, 2021, and November 14, 2021, and for which the solicitation was issued before October 15, 2021, the guidance states that agencies are encouraged to include the clause but are not required to do so.

considered fully vaccinated if they have received any other "COVID-19 vaccines that have been listed for emergency use by the World Health Organization." *Id.* at 4.

83. On October 18, 2021, the Cargo Airline Association representing UPS, FedEx, and others warned the White House that the Federal Contractor Vaccine Mandate will cause severe disruption and exacerbate the nation's labor shortage and supply chain problems. Natasha Korecki, "Biden's vaccine mandate has cargo giants in pre-holiday panic," *Politico*, Oct. 21, 2021, https://www.politico.com/news/2021/10/21/joe-biden-vaccine-mandate-supply-chain-516682 (last visited Jan. 3, 2022). By October 31, 2021, other companies and associations in the aerospace, distribution, defense, and trucking industries expressed similar misgivings and suggested that "the cost of the mandate is not worth the government's checks." Hailey Fuchs and Natasha Korecki, "Companies mull ending government contracts over vaccine mandates," *Politico*, Oct. 31, 2021, available at https://www.politico.com/news/2021/10/31/government-contracts-vaccine-mandate-517857 (last visited Jan. 3, 2022).

84. In response to these concerns, Defendants announced on November 4, 2021, that the deadline for contractor and subcontractor employees to be fully vaccinated would be extended. *See* The White House, *Fact Sheet: Biden Administration Announces Details of Two Major Vaccination Policies* (Nov. 4, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/ (last visited Jan. 3, 2022). On November 10, the Task Force issued updated guidance ("Updated Task Force Guidance"), which contained identical requirements as the original Task Force Guidance except that it delayed the compliance deadline to January 18, 2021. *See* Safer Federal Workforce Task Force, COVID-19 Workplace Safety: Guidance for Federal

Contractors and Subcontractors, at 5 (Nov. 10, 2021) (Attachment C). The Task Force also moved the Q&A Section to a website: https://www.saferfederalworkforce.gov/faq/contractors/.

C. The OMB Determinations

85. On September 28, 2021, OMB published a notice in the Federal Register in which it conclusorily "determined that compliance by Federal contractors and subcontractors with COVID-19 workplace safety protocols detailed in the [Task Force] guidance will improve economy and efficiency by reducing absenteeism and decreasing labor costs for contractors and subcontractors working on or in connection with a Federal Government contract." 86 Fed. Reg. 53691, 53692.

86. On November 16, 2021, OMB rescinded its September 28, 2021 Determination and issued a new Determination, which claimed the goal of the Federal Contractor Vaccine Mandate "is to reduce the spread of COVID-19 among contractor employees" in order to reduce the net cost of COVID-related absenteeism for workers of federal contractors, which "would be expected to be passed to the Federal Government." *Determination of the Acting OMB Director Regarding the Revised Safer Federal Workforce Task Force Guidance for Federal Contractors and the Revised Economy and Efficiency Analysis*, 86 Reg. 63,418, 63,421-22 (Nov. 16, 2021) ("Revised Determination") (Attachment D). While OMB recognized "that vaccine mandates may lead some workers to quit their jobs rather than comply, which could create some cost associated with replacing them," it concluded, without any analysis, that such separation will be rare and therefore would not outweigh the benefits of reducing COVID-related absenteeism.

87. The Revised Determination did not acknowledge, much less consider, the fact that Defendants delayed implementation of the Federal Contractor Vaccine Mandate in response to warnings by associations and companies that the mandate would cause workforce and supply-

chain disruptions—with some companies stating that they prefer to terminate federal contracts rather than face compliance costs. *See supra* ¶ 83.

88. The Revised Determination also asserted "there are urgent and compelling circumstances that justify departing from the notice-and-comment and delayed-effective-date requirements in 41 U.S.C. 1707." *Id.* at 63,424. But it did not explain how this claim can be reconciled with Defendants' decision to delay the implementation of the Federal Contractor Vaccine Mandate. *See supra* ¶ 84.

89. The Revised Determination purports to adopt the Task Force Guidance under the President's authority pursuant to 40 U.S.C. § 101. *Id.* at 63,421.

90. Neither the Task Force Guidance nor OBM's Revised Determination explained why a one-size-fits-all cost-benefit balancing is appropriate, rather than letting individual companies, which better understand their own workers' circumstances and preferences, decide how to trade off the benefits of reducing COVID-related absenteeism against the cost of worker separation.

91. Defendants also failed to explain why employees who work remotely from their own residences, and thus have no risk of contributing to "the spread of COVID-19 among contractor employees," 86 Fed. Reg. at 63,421, must receive the vaccine or else lose their jobs.

92. Nor did Defendants address—much less reasonably explain—why natural immunity should not be considered an adequate alternative to vaccination. By all indications, natural immunity confers superior resistance to COVID-19 than any of the currently available vaccines. Joint Decl. ¶¶ 15-24. Multiple extensive, peer-reviewed studies comparing naturally acquired and vaccine-acquired immunity have concluded overwhelmingly that the former provides equivalent or greater protection against severe infection than immunity generated by mRNA

vaccines (BioNTech and Moderna). Joint Decl. ¶¶ 18-23. Natural immunity *a fortiori* confers far greater protection than the Sinovac Vaccine and COVISHIELD vaccines, which have been approved by the World Health Organization and thus would satisfy the Task Force Guidance's vaccine requirement.[4]

D. FAR Council Memo

93. On September 30, 2021, the FAR Council issued a memorandum providing instructions for agencies responsible for ensuring contractor and subcontractor compliance with the vaccination requirement until the FAR could be amended. FAR Council Memo, https://www.whitehouse.gov/wp-content/uploads/2021/09/FAR-Council-Guidance-on-Agency-Issuance-of-Deviations-to-Implement-EO-14042.pdf (last visited Jan. 3, 2022). Under the FAR Memo, the vaccination requirement applies only to contracts awarded on or after November 15, 2021; new solicitations issued on or after October 15, 2021; and extensions to or renewals of existing contracts exercised on or after October 15, 2021. *Id.* at 2.

94. The FAR Council also attached a deviation clause that contractors were encouraged to insert into their current contracts. *Id.* at 4-5.

[4] The Chinese Sinovac Vaccine, which has been approved by WHO prevents *symptomatic* disease in just 51% of those who received it. *See WHO Validates Sinovac COVID-19 Vaccine for Emergency Use and Issues Interim Policy Recommendations*, WHO.INT (June 1, 2021), *available at* https://www.who.int/news/item/01-06-2021-who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations (last visited Jan. 3, 2022). The COVISHIELD vaccine, manufactured by the Serum Institute of India and South Korea's SK Bioscience Co., Ltd., is also WHO-approved. It has a mere 70.42% efficacy against *symptomatic* COVID-19 infection, which fell to 62.10% in individuals who received two standard doses. *See Recommendation on Emergency Use Listing on COVISHIELD Submitted by SIIPL*, WHO (Feb. 26, 2021), *available at* bit.ly/3rNjnPo (last visited Jan. 3, 2022).

95. The FAR Council issued these instructions and Deviation Clause to all Chief Acquisition Officers, Senior Procurement Officers, the Defense Acquisition Regulations Council, and the Civilian Agency Acquisition Council. The memorandum stipulated that one of the stated purposes of the FAR Deviation Clause and guidance, which was published the next day, was to "maximize the goal of getting more people vaccinated and decrease the spread of Covid-19."

IV. Plaintiffs Have Experienced, and Will Continue to Experience, Concrete and Particularized Harm as a Direct Consequence of the Federal Contractor Vaccine Mandate

96. The Plaintiffs either must receive a COVID-19 vaccine or face adverse employment actions, including loss of employment. Accordingly, Plaintiffs' personal autonomy and livelihoods are being infringed. Not only does the Federal Contractor Vaccine Mandate threaten Plaintiffs with the loss of their current jobs, but as long as it is in effect, Plaintiffs will be unable to obtain new employment working for a federal contractor or subcontractor.

97. By threatening adverse professional and personal consequences, the Federal Contractor Vaccine Mandate not only directly and palpably harms Plaintiffs' bodily autonomy and dignity, but it forces them to choose between their livelihoods—upon which they and their families rely—and their bodily autonomy.

CLASS ACTION ALLEGATIONS

I. The Primary Class

98. ***Class Definition.*** Plaintiffs brings this action on behalf of themselves and all other similarly situated individuals who work for a covered federal contractor or subcontractor ("the Class"), pursuant to Federal Rule of Civil Procedure 23. The Class is defined as all employees of federal contractors and subcontractors who are subject to the Federal Contractor Vaccine Mandate and who object to receiving the vaccine.

99. For purposes of this Complaint and because this suit is being brought as a class action, references to any of the Plaintiffs should be construed not just as applying to the named Class Representatives but all Class Members even where not explicitly stated.

100. ***Numerosity.*** The exact size of the class is unknown. The United States Department of Labor estimates that "workers employed by federal contractors" make up "approximately one-fifth of the entire U.S. labor force." U.S. Dep't of Labor, *History of Executive Order 11246*, https://www.dol.gov/agencies/ofccp/executive-order-11246/regulations (last visited Jan. 3, 2022). As there are over 160 million workers in the U.S. work force,[5] that estimate implies there are over 32 million employees of federal contractors and subcontractors. Even if the desire to take a COVID-19 vaccine runs at about 90% among such individuals, that would still leave millions of potential Class Members. Hence, the numerosity requirement in Fed. R. Civ. P. 23(a)(1) is readily satisfied.

101. ***Commonality.*** There are multiple questions of law and fact common to the Class, including but not limited to:

a. Whether the Federal Contractor Vaccine Mandate constitutes an unlawful exercise of legislative power by the executive branch, and as such violates Plaintiffs' rights to be governed by laws enacted by their elected representatives (rather than appointed bureaucrats).

b. Whether the Federal Contractor Vaccine Mandate violates the Competition in Contracting Act's requirement that federal agencies "provide for full and open competition through the use of competitive procedures." 41 U.S.C. § 3001.

[5] U.S. Bureau of Labor Statistics, *Table A-1. Employment status of civilian population by sex and age*, https://www.bls.gov/news.release/empsit.t01.htm (Last modified Dec. 3, 2021).

c. Whether the Federal Contractor Vaccine Mandate constitutes an unconstitutional infringement on Plaintiffs' rights to bodily autonomy and to decline unnecessary medical treatment under the Fifth and Ninth Amendments to the United States Constitution;

d. Whether the Federal Contractor Vaccine Mandate violates Plaintiffs' federal statutory rights under the Emergency Use Authorization ("EUA") statute; and

e. Whether the Federal Contractor Vaccine Mandate is arbitrary and capricious, in violation of the Administrative Procedure Act ("APA").

As a result, the commonality requirement of Fed. R. Civ. P. 23(a)(2) is met here.

102. ***Typicality.*** Plaintiffs' claims are typical of the Class, as they all work for federal contractors that are required to ensure all employees and subcontractors satisfy the Federal Contractor Vaccine Mandate. They all object to the Federal Contractor Vaccine Mandate on the grounds that it violates their constitutional and statutory rights as described above. As a result, the typicality requirement of Fed. R. Civ. P. 23(a)(3) is met.

103. ***Adequacy of Representation.*** Plaintiffs will fairly and adequately protect the interests of the Class Members. Plaintiffs' interests are aligned with, and not antagonistic to, those of the other members of the Class. Additionally, Plaintiffs are seeking identical declaratory and injunctive relief that would benefit all putative Class Members. Plaintiffs have also retained counsel competent and experienced in the prosecution of class-action litigation to represent themselves and the Class. As a result, the adequacy-of-representation requirement of Fed. R. Civ. P. 23(a)(4) is met.

104. ***Fed. R. Civ. P. 23(b)(2) Class Type.*** Certification for injunctive and declaratory relief is appropriate under Rule 23(b)(2) because Defendants have acted, principally by mandating

that employees and subcontractors of federal contractors receive a COVID-19 vaccine, on grounds that generally apply to the whole class. This also makes temporary, preliminary, and permanent injunctive relief appropriate "respecting the class as a whole." Fed. R. Civ. P. 23(b)(2).

105. ***Class Action Superiority & Efficiency*.** While it is not necessary to plead as part of a Rule 23(b)(2) class action, class-wide treatment of the common issues presented by this suit against Defendants in a single forum represents a superior means of determining Defendants' liability to each Class Member than potentially millions of individual lawsuits. As a result, class-wide adjudication of Defendants' liability followed by the grant of undifferentiated declaratory and injunctive relief is the most efficient means of adjudication.

II. The Natural Immunity and Remote Worker Subclasses

106. The Federal Contractor Vaccine Mandate is unlawful for the entire Class, but there are two subclasses for whom it is particularly nonsensical and harmful: those who have natural immunity because they have contracted and recovered from COVID-19 and those who work remotely on a full-time basis.

107. ***Natural Immunity Subclass Definitions.*** Plaintiffs Vanderstelt, Gardner, Fant, Villegas, Merz, Van Riper, Hand, Moore, and Bulson brings this action on behalf of themselves and all others similarly situated as part of the Natural Immunity Subclass, pursuant to Federal Rule of Civil Procedure 23. The Natural Immunity Subclass is defined as individuals who are members of the Class and who have acquired natural immunity due to recovery from a prior infection of COVID-19.

108. ***Remote Worker Subclass Definitions.*** Plaintiffs Merz, Moore, Bulson, and Gateley brings this action on behalf of themselves and all others similarly situated as part of the Remote Worker Subclass, pursuant to Federal Rule of Civil Procedure 23. The Remote Worker Subclass

is defined as individuals who are members of the Class and who work full-time at a home office or other remote location where there are no co-workers from or to whom COVID-19 could be spread.

109. ***Numerosity.*** The exact sizes of the Natural Immunity and Remote Worker Subclasses are unknown. Over 30 million Americans work for federal contractors—*i.e.*, one-fifth of the workforce. *Supra* ¶ 69. At least one in three Americans have recovered from COVID-19,[6] and approximately one in four Americans work remotely full-time.[7] As such, there likely are millions of Americans working for federal contractors who have acquired natural immunity due to recovering from COVID-19, work remotely, or both. This leaves hundreds of thousands of potential Natural Immunity and Remote Worker Subclass Members even if the desire to take a COVID-19 vaccine runs at about 90% among naturally immune and remote workers. Hence, the numerosity requirement in Fed. R. Civ. P. 23(a)(1) is readily met.

110. ***Commonality.*** There are multiple questions of law and fact common to the Naturally Immune and Remote Worker Subclasses, respectively. These include questions common to the Class as well as, *inter alia*:

a. For the Naturally Immune Subclass, whether the Federal Contractor Vaccine Mandate violates their due process rights by irrationally favoring workers with vaccine-based immunity while irrationally disfavoring workers with natural immunity.

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[66] Pein Sen, et al., *Burden and characteristics of COVID-19 in the United States during 2020*, 598 Nature 338 (2021), https://www.nature.com/articles/s41586-021-03914-4 (last visited Jan. 3, 2022).

[77] Gallup, Remote Work Persisting and Trending Permanent, https://news.gallup.com/poll/355907/remote-work-persisting-trending-permanent.aspx (last visited Jan. 3, 2022).

b. Whether the Federal Contractor Vaccine Mandate is narrowly tailored to serve the proffered government interest in reducing the spread of COVID-19 in contractors' workplaces if it applies to naturally immune and remote workers who do not contribute to the spread COVID-19.

c. Whether it is arbitrary and capricious for Defendants to promulgate the Federal Contractor Vaccine Mandate without due consideration and explanation for why the mandate applies to naturally immune and remote workers who do not contribute to the spread COVID-19 in contractors' workplaces.

As a result, the commonality requirement of Fed. R. Civ. P. 23(a)(2) is met here.

111. ***Typicality.*** Plaintiffs Vanderstelt, Gardner, Fant, Villegas, Merz, Van Riper, Hand, Moore, and Bulson's claims are typical of the Natural Immunity Subclass, as they are all Members of the Class who have acquired natural immunity due to recovering from COVID-19. Plaintiffs Merz, Moore, Bulson, and Gateley's claims are typical of the Remote Worker Subclass, as they are all Members of the Class who work full-time from their homes or another remote location. As a result, the typicality requirement of Fed. R. Civ. P. 23(a)(3) is met.

112. ***Adequacy of Representation.*** Plaintiffs will fairly and adequately protect the interests of the Natural Immunity and Remote Worker Subclass Members. Plaintiffs' interests are aligned with, and not antagonistic to, those of the other members of their Subclasses. Additionally, Plaintiffs are seeking identical declaratory and injunctive relief that would benefit all putative Class Members. Plaintiffs have also retained counsel competent and experienced in the prosecution of class-action litigation to represent themselves and the Class. As a result, the adequacy-of-representation requirement of Fed. R. Civ. P. 23(a)(4) is met.

113. ***Fed. R. Civ. P. 23(b)(2) Class Type.*** Certification for injunctive and declaratory relief is appropriate under Rule 23(b)(2) because Defendants have acted (principally by mandating that employees and subcontractors of federal contractors receive and provide proof of vaccination) and declined to act (via their refusal to recognize natural immunity or remote work as exemptions) on grounds that generally apply to the respective Subclass. This also makes temporary, preliminary, and permanent injunctive relief appropriate respecting each Subclass as a whole. Fed. R. Civ. P. 23(b)(2).

114. ***Class Action Superiority & Efficiency*.** While it is not necessary to plead as part of a Rule 23(b)(2) class action, subclass-wide treatment of the common issues presented by this suit against Defendants in a single forum represents a superior means of determining Defendants' liability to each Subclass Member than potentially hundreds of thousands of individual lawsuits. As a result, class-wide adjudication of Defendants' liability followed by the grant of undifferentiated declaratory and injunctive relief is the most efficient means of adjudication.

CLAIMS FOR RELIEF

Count I: Unconstitutional Divesting of Legislative Powers

115. Plaintiffs reallege and incorporate by reference the foregoing allegations as if fully set forth herein.

116. Pursuant to Article I, § 1 of the U.S. Constitution, "[a]ll legislative powers herein granted shall be vested in a Congress of the United States." Only Congress may engage in lawmaking. "Congress is not permitted to abdicate or to transfer to others the essential legislative functions with which it is thus vested." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529–30 (1935). The prohibition against divesting of legislative power is not only necessary to protect one branch of government from intrusions by another, but "[t]he structural principles secured by the separation of powers protect the individual as well." *Dep't of Transp. v. Ass'n of*

Am. Railroads, 575 U.S. 43, 55 (2015) (quoting *Bond v. United States*, 564 U.S. 211, 222 (2011)). Individuals have a right to be subject to laws enacted by their elected representatives in Congress. That right is violated when executive branch officials enact legislation through orders, regulation, guidance and other unconstitutional methods.

117. While current precedent permits Congress to delegate some power to executive officials, the statutory delegation must include intelligible principles to which the delegatee "is directed to conform." *J.W. Hampton, Jr., & Co v. United States*, 276 U.S. 394, 409 (1928). Intelligible and judicially administrable principles are necessary to ensure a Congressional delegation does not confer unfettered discretion to the executive branch and thus cross into unconstitutional divesting of legislative power.

118. The precatory statement of purpose in the Procurement Act "to provide the Federal Government with an economical and efficient [procurement] system" is not a clear directive and provides no intelligible principles. *See* 40 U.S. Code § 101. As such, the President cannot rely on it to impose an intrusive and sweeping vaccine mandate over 20 percent of the U.S. workforce.

119. Defendants' attempt to impose sweeping controls on one-fifth of the economy via procurement is a question of deep economic and political significance, and Congress did not intend—nor does the Procurement Act allow—the President to exercise such sweeping authority under the guise of "procurement" in the absence of clear and explicit congressional authorization. *See Ala. Ass'n of Realtors*, 141 S. Ct. 2485, 2488.

120. Two federal courts have already found precisely this. In *Kentucky v. Biden*, the court explained that "despite Congress's broad delegation of power under the FPASA, the President's authority is not absolute." 2021 WL 5587446, at *6. Recognizing that the statute's goal was to create "an economical and efficient system for … *procurement and supply*," the court

opined that "it strains credulity that Congress intended the FPASA, a procurement statute, to be the basis for promulgating a public health measure such as mandatory vaccination." *Id.* (emphasis in original).

121. The court concluded that "[a]lthough Congress used its power to delegate procurement authority to the president to promote economy and efficiency [in] federal contracting, this power has limits. … Defendants cannot go beyond the authority authorized by Congress … Accordingly, the Court finds that the President exceeded his authority under the FPASA." *Id.* at 14. The court in *Georgia v. Biden* reached the same conclusion, explaining that "EO 14042 goes far beyond addressing administrative and management issues in order to promote efficiency and economy in procurement and contracting, and instead, in application, works as a regulation of public health, which is not clearly authorized under the Procurement Act." 2021 WL 5779939, at *9.

122. That same law faces the same delegation defect here.

123. In the alternative, should the power here asserted be deemed to have been conferred by such statutory language, the Federal Contractor Vaccine Mandate must be struck because the animating law violates the non-delegation doctrine by failing to contain a limiting or even intelligible principle by which the Court can discern its content and direction and decide whether it exceeds the scope of the delegation authorized.

Count II: Lack of Nexus to Efficient and Economical Federal Procurement

124. Plaintiffs reallege and incorporate by reference the foregoing allegations as if fully set forth herein.

125. Assuming *arguendo* that the Procurement Act could be read to show that Congress delegated powers to the President to regulate the federal procurement system, the Federal Contractor Vaccine Mandate exceeds the scope of delegation.

126. The purpose of the Procurement Act is to provide the Federal Government with an "economical and efficient system" for, among other things, procuring good and services. 40 U.S.C. § 101. The Procurement Act permits the President to prescribe certain policies and directives within the scope of the Act. 40 U.S.C. § 121. The President's power under the Procurement Act must be exercised in a manner consistent with the structure and purposes of the statute that delegates that power—namely, efficiency and economy in procurement. *See Chrysler*, 441 U.S. at 304.

127. Executive Orders issued pursuant to the President's authority under the Procurement Act are subject to judicial review. *Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1329 (D.C. Cir. 1996). The President may only issue executive orders that have a nexus to the purposes of the Procurement Act. When the President exceeds his authority under the Procurement Act, he acts *ultra vires* and the Executive Order is unconstitutional.

128. There is no nexus between Executive Order 14042 (or the Task Force Guidance implementing it) and the Procurement Act's purpose of providing an "economical and efficient system" of procurement. *See* 40 U.S.C. § 101.

129. The *Kentucky v. Biden* court adopted precisely this position: "if a vaccination mandate has a close enough nexus to economy and efficiency in federal procurement, then the

statute could be used to enact virtually any measure at the president's whim under the guise of economy and efficiency." 2021 WL 5587446, at *7. The *Georgia v. Biden* court agreed that "EO 14042's directives and resulting impact radiate too far beyond the purposes of the Procurement Act and the authority it grants to the President." 2021 WL 5779939, at *10.

130. In fact, the Federal Contractor Vaccine Mandate will have a deleterious effect on economy and efficiency by causing large-scale layoffs. Defendants' recognition that such deleterious effects would occur is evinced by their decision to delay the Federal Contractor Vaccine Mandate in response to warnings raised by industry actors that the mandate would cause workforce and supply-chain disruptions. A mandate requiring vaccination has no direct connection to efficient federal procurement, and indeed would cause inefficiencies and delay, and therefore it does not lie reasonably within the contemplation of the Procurement Act. *See Becerra*, 2021 WL 5609846, at *13 (finding that CMS mandate is arbitrary and capricious because, *inter alia*, the implementing statute was designed to protect patients while "the CMS Mandate would have the opposite effect due to the loss of healthcare workers and funding to healthcare facilities"); *see also Missouri*, 2021 WL 5564501, at *11 ("[b]y dispensing with [notice and comment] requirements, CMS ignored evidence showing that the mandate threatens devastating consequences to healthcare providers, staff, and patients throughout the nation").

131. Moreover, the President's power under the Procurement Act "to provide … an economical and efficient system" of procurement, *see* 40 U.S. Code § 101, must be interpreted in light of Congress's subsequent enactment of the CICA, which requires federal procurement to follow "full and open competition through the use of competitive procedures." *See* 41 U.S.C. § 3301. By excluding companies with unvaccinated workers from bidding on procurement

contracts, even if those workers are naturally immune and/or work from home, Defendants violate the CICA's "full and open competition" requirement.

COUNT III: VIOLATION OF THE CONSTITUTIONAL RIGHT TO REFUSE UNWANTED AND MEDICALLY UNNECESSARY CARE

132. Plaintiffs reallege and incorporate by reference the foregoing allegations as if fully set forth herein.

133. The Federal Contractor Vaccine Mandate requires Plaintiffs to take a vaccine without their consent—and in the case of naturally immune Plaintiffs, against the medical advice of experts—thereby depriving them of their constitutional right to refuse unwanted medical care.

134. Presenting the Federal Contractor Vaccine Mandate as an option—since the worker can accept being fired instead of vaccinating—does not cure its unconstitutionality. Under the unconstitutional-conditions doctrine, Defendants cannot impair Plaintiffs' right to refuse medical care through indirect forms of coercion any more than it could through an explicit mandate. *See, e.g., Koontz v. St. Johns River Water Mgmt. Dist*., 570 U.S. 595 (2013) ("[U]nconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them"); *Memorial Hosp. v. Maricopa Cty*., 415 U.S. 250 (1974) (finding that state residency requirement impinged on the constitutionally guaranteed right to interstate travel, while lacking a compelling state interest, and thus was unconstitutional).

135. Unconstitutional conditions claims need not establish that a challenged government policy amounts to coercion. Instead, it is sufficient that the state policy burdens a constitutional right by imposing undue pressure on an otherwise voluntary choice with a nexus to the exercise of a constitutional right. *See Garrity v. New Jersey*, 385 U.S. 493, 497–98 (1967) ("The option to lose their means of livelihood or [forfeit a constitutional right] is the antithesis of free choice.").

136. The Supreme Court has recognized that the Ninth and Fourteenth Amendments protect an individual's right to privacy. A "forcible injection … into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" *Washington v. Harper*, 494 U.S. 210, 229 (1990). The common-law baseline is also a relevant touchstone out of which grew the relevant constitutional law. *See, e.g., Cruzan v. Dir., Mo. Dep't of Public Health*, 497 U.S. 261, 278 (1990) ("'At common law, even the touching of one person by another without consent and without legal justification was a battery'"). *See* W. Keeton, D. Dobbs, R. Keeton, & D. Owen, PROSSER AND KEETON ON LAW OF TORTS § 9, pp. 39-42 (5th ed. 1984); *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129-130 (1914) (Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.").

137. The Fifth Amendment's Due Process Clause is applicable here, not the Fourteenth Amendment's Due Process Clause (which applies only to the States). But the same substantive due process right to privacy is protected by Fifth Amendment due process of law. *See Webster v. Doe*, 486 U.S. 592, 601-02 (1988) (CIA employee was permitted to advance claims, inter alia, that he was being deprived of his constitutional rights to privacy under the Fifth Amendment even though he possessed no right of judicial review under the Administrative Procedure Act to contest his discharge).

138. Subsequent Supreme Court decisions have made explicit that the Constitution protects a person's right to "refus[e] unwanted medical care." *Cruzan*, 497 U.S. at 278; *King v. Rubenstein*, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same).

139. This right is "so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment." *Washington v. Glucksberg*, 521 U.S. 702, 722 n.17 (1997). Again, as noted above in paragraph 137, there is no reason to confine that conclusion to cases involving the Fourteenth Amendment's Due Process Clause rather than applying that conclusion to the Fifth Amendment's Due Process Clause as well.

140. The Court has explained that the right to refuse medical care derives from the "well-established, traditional rights to bodily integrity and freedom from unwanted touching." *Vacco v. Quill*, 521 U.S. 793, 807 (1997).

141. The Ninth Amendment similarly protects the rights to privacy and bodily integrity. *See Griswold v. Connecticut*, 381 U.S. 479, 488 (1965) (Goldberg, J., concurring) ("The language and history of the Ninth Amendment reveal that the Framers of the Constitution believed that there are additional fundamental rights, protected from governmental infringement, which exist alongside those fundamental rights specifically mentioned in the first eight constitutional amendments.").

142. Coercing employees to receive a vaccine (whether approved under an EUA or fully by the FDA) for a virus that in most cases presents a near-zero risk of death violates the liberty and privacy interests that the Fifth and Ninth Amendments protect. This is especially so for naturally immune and remote working Plaintiffs who are exceedingly unlikely to infect or be infected by co-workers.

143. "Government actions that burden the exercise of those fundamental rights or liberty interests [life, liberty, property] are subject to strict scrutiny, and will be upheld only when they are narrowly tailored to a compelling governmental interest." *Does v. Munoz*, 507 F.3d 961, 964 (2007).

144. Defendants' proffered interest in "reducing absenteeism and decreasing labor costs for contractors and subcontractors working on or in connection with a Federal Government contract," *see* 86 Fed. Reg. 63,418, is not a compelling interest that could overcome Plaintiffs' constitutional right to refuse unwanted medical procedures. If it were, Defendants could, for instance, require the one-fifth of the U.S. workforce employed by federal contractors to undertake all sorts of interventions that could improve their health—and thereby reduce health-related absenteeism—such as exercise, diet, and surgical procedures like liposuction.

145. Additionally, the Federal Contractor Vaccine Mandate is not narrowly tailored, especially as applied to federal-contractor workers who do not perform work on the federal contract, are naturally immune, and/or work remotely. *See Becerra*, 2021 WL 5609846 (W.D. La. Nov. 30, 2021) ("the rejection of natural immunity as an alternative is puzzling").

146. Defendants' justification for their refusal to provide an exception for full-time remote workers is as follows:

> **Q11: How does this Guidance apply to covered contractor employees who are authorized under the covered contract to perform work remotely from their residence?**
>
> A: An individual working on a covered contract from their residence is a covered contractor employee, and must comply with the vaccination requirement for covered contractor employees, even if the employee never works at either a covered contractor workplace or Federal workplace during the performance of the contract. A covered contractor employee's residence is not a covered contractor workplace, so while in the residence the individual need not comply with requirements for covered contractor workplaces, including those related to masking and physical distancing, even while working on a covered contract.

This conclusory question-and-answer provides no explanation of *why* an individual who works from home, and therefore poses no risk spreading COVID-19 to co-workers must vaccinate to reduce workplace absenteeism.

147. Likewise, all Defendants say to justify refusing to provide an exception for natural immunity to the Federal Contractor Vaccine Mandate is this:

> **Q5: Are covered contractor employees who have a prior COVID-19 infection required to be vaccinated?**
>
> A: Yes, covered contractor employees who have had a prior COVID-19 infection are required to be vaccinated. More information from CDC can be found here [providing hyperlink].

Task Force Guidance at 11. The hyperlink leads to a to CDC website with an FAQ stating that "people get better protection by being fully vaccinated compared with having had COVID-19," citing a single study from Kentucky that fails to support that proposition.[8] This FAQ does not dispute that individual with natural immunity pose lower risk of workplace infection. Nor does it explain what compelling interest is served by forcing them to take an unwanted vaccine to further reduce the risk of workplace infection. Additionally, the study from Kentucky upon which the FAQ has been both wrongly interpreted and incorrectly portrayed by the media. *See* Joint Decl. ¶ 37.

148. The CDC's FAQ, relied on in the Task Force Guidance, ignores the far more substantial research establishing that recovery from a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. Joint Decl. at ¶¶ 15-24; Nabin K. Shrestha, et al., Necessity of COVID-19 Vaccination in Previously Infected Individuals, MedRxiv (June 5th, 2021), available at https://bit.ly/2TFBGcA (last visited Jan. 3, 2022); *see also* Yair Goldberg, et al., Protection of Previous SARS-Cov-2 Infection Is Similar to That of BNT162b2 Vaccine Protection: A Three-Month Nationwide Experience from Israel, MedRxiv (Apr. 20, 2021), available at https://bit.ly/3zMV2fb (last visited Jan. 3, 2022); Michael

[8] CDC, Frequently Asked Questions about COVID-19 Vaccination, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (last visited Jan. 3, 2022).

Smerconish, Should Covid Survivors and the Vaccinated Be Treated the Same?: CNN Interview with Jay Bhattacharya, Professor of Medicine at Stanford University (June 12, 2021), available at https://cnn.it/2WDurDn (last visited Jan. 3, 2022); Marty Makary, The Power of Natural Immunity, Wall Street Journal (June 8, 2021), available at https://on.wsj.com/3yeu1Rx (last visited Jan. 3, 2022).

149. In recognition of the highly protective character of natural immunity, the European Union has recognized "a record of previous infection" as a substitute for any vaccine passport requirements. Even France's controversial and restrictive mandate on the ability to participate in daily life focuses on a person's immunity rather than their vaccine status—treating natural and vaccine immunity as equivalent. *See, e.g.*, Clea Callcutt, *France Forced to Soften Rules After Coronavirus Green Pass Backlash*, Politico (July 20, 2021), available at https://politi.co/3f9AZzS (last visited Jan. 3, 2022).

150. Similarly, the United States requires everyone, including its citizens, to provide proof of a negative COVID-19 test before returning to the country from abroad. Yet, documentation of recovery suffices as a substitute, although proof of vaccination does not. *See* Requirement of Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States, CDC (Dec. 17, 2021), available at https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-international-air-travelers.html (last visited Jan. 3, 2022).

151. Recent data from Israel suggests that individuals who receive the BioNTech Vaccine can pass the virus onto others a mere few months after receiving it, casting doubt on any claim that the vaccine prevents spread of the virus, or at least any claim that it does so to a greater extent than naturally acquired immunity. *See Missouri*, 2021 WL 5564501, at *8 (observing that

"the lack of data regarding vaccination status and transmissibility—in general—is concerning" and "CMS also admits that the continued efficacy of the vaccine is uncertain").

152. Another indication that the Federal Contractor Vaccine Mandate lacks any constitutional validity is that many of the vaccines that the Task Force accepts, such as the Sinovac and Sinopharm vaccines, are much less effective when it comes to preventing infection than natural immunity.

153. Indeed, the refusal to recognize naturally acquired immunity is a phenomenon unique to COVID-19. Even the United States military exempts individuals who can demonstrate naturally acquired immunity to the disease in question from its requisite vaccines . *See* "Immunization Exception Guidance," The Official Website of the Military Health System, available at https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Clinical-Consultation-Services/Exemption-Guidance (last visited Jan. 3, 2022).

154. Many states exempt children who have had a disease from getting the vaccine designed to prevent that disease. *See, e.g.*, 12 VA. ADMIN. CODE § 5-110-80 (2021) (regulation mandating vaccination of school children for measles, mumps, rubella, and varicella (chickenpox) *explicitly exempts* from the requirements those who can demonstrate existing immunity through serological testing that measures protective antibodies.); MICH. ADMIN. CODE r. 325.176 (2021) (same).

Count IV: Violation of the Equal Protection Component of the Due Process Clause of the Fifth Amendment

155. Plaintiffs reallege and incorporate by reference all the foregoing allegations as though fully set forth herein.

156. The equal protection component of the Due Process Clause of the Fifth Amendment guarantees Plaintiffs' rights to equal protection under the law. *See United States Dep't of Agric. v.*

Moreno, 413 U.S. 528 (1973) ("While the Fifth Amendment contains no equal protection clause, it does forbid discrimination that is so unjustifiable as to be violative of due process.") (cleaned up).

157. The Federal Contractor Vaccine Mandate treats unequally the two forms of immunity to COVID-19, irrationally favoring workers with vaccine-based immunity while irrationally disfavoring workers with natural immunity.

158. There is no rational basis in the scientific record for treating vaccine-based immunity as always and in everyone superior to natural immunity. *See City of Cleburne v. Cleburne Living Ctr., Inc.*, 472 U.S. 432 (1985). As discussed above and noted by several courts recently, the science establishes that natural immunity is as good or superior to vaccine-induced immunity. Hence, it is unconstitutional for the Federal Contractor Vaccine Mandate to ignore the issue of natural immunity and to compel federal contractors to impose employment discipline on those who have naturally acquired immunity.

159. Equal protection problems are compounded because individuals with naturally acquired immunity are at a disadvantage when it comes to vaccination, since immunization poses a greater risk of harm to them than to those who are unvaccinated and have not acquired immunity naturally. Thus, through no fault of their own, Plaintiffs who are naturally immune are in a position where they have to expose themselves to a heightened risk of adverse side effects.

160. Equal protection problems are also compounded because the Federal Contractor Vaccine Mandate effectively creates two classes of workers—those allowed relative freedom to continue to work and those denied such freedoms and saddled with employment fetters and discipline, without any rational justification.

Count V: Violation of the Fifth Amendment's Due Process Clause

161. Plaintiffs reallege and incorporate by reference all of the foregoing allegations as though fully set forth herein.

162. The Fifth Amendment prohibits the "depriv[ation] of life, liberty, or property, without due process of law." The "touchstone of due process is protection of the individual against arbitrary action of government." *Wolff v. McDonnell*, 418 U.S. 539, 558 (1974).

163. Plaintiffs have a liberty interest in pursuing their careers or professions and in deciding whether or not to receive EUA-approved, and possibly medically unnecessary or harmful, vaccines.

164. The Federal Contractor Vaccine Mandate deprives Plaintiffs of their rights to pursue their careers and to refuse EUA-approved vaccines without a hearing and without any valid public health rationale. *See Goldberg v. Kelly*, 397 U.S. 254 (1970) (termination of welfare benefits without a hearing violated procedural due process requirements.). Accordingly, the Federal Contractor Vaccine Mandate violates Plaintiffs' procedural due process rights

Count VI: Violation of the Federal Emergency Use Authorization Statute

165. Plaintiffs reallege and incorporate by reference all the foregoing allegations as though fully set forth herein.

A. The EUA Statute Invalidates Defendants' Federal Contractor Vaccine Mandate

166. The Federal Contractor Vaccine Mandate requires Plaintiffs and others similarly situated to receive a vaccine in order to continue working for a federal contractor. Plaintiffs and others must also divulge personal medical information to their employers and are threatened with disciplinary action if they decline to comply with these arbitrary mandates.

167. The Federal Contractor Vaccine Mandate thus coerces or, at the very least, unduly pressures, Plaintiffs and others like them into getting vaccines that FDA has approved only for emergency use.

168. The EUA statute mandates informed and voluntary consent. *See Rumsfeld*, 2005 WL 1124589, *1 (allowing use of anthrax vaccine pursuant to EUA "on a voluntary basis"). *See also* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). Recipients of products approved for emergency use must be informed of the "option to accept or refuse administration" and of the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown." *Id*.

169. Thus, the federal EUA statute creates a statutory right to refuse EUA products, including the EUA vaccines, without undue coercion. The Federal Contractor Vaccine Mandate violates this statutory right to refuse because it forces Plaintiffs to sustain significant injury to their livelihoods if they refuse the vaccine.

170. Congress has explicitly authorized the President to waive the statutory right to refuse "a product authorized for emergency use under … the Federal Food, Drug, and Cosmetic Act [as] to members of the armed forces," but "only if the President determines, in writing, that complying with such requirement is not in the interest of national security." 10 U.S.C. § 1107a(a)(1). The President has not yet made such a determination and thus may not even require members of the armed forces to take an EUA vaccine.

171. In stark contrast, Congress has not authorized the President to waive civilians' statutory rights to refuse an EUA product under any circumstances, including their federal contractor status.

B. The FDA's Approval of the Comirnaty Vaccine Does Not Save the Task Force's Federal Contractor Vaccine Mandate

172. That the Comirnaty Vaccine has received full FDA approval does not foreclose the argument presented in this count that a federal statute trumps EO 14,042 and the Task Force Guidance issued under the EO's umbrella. That is because this approval does not extend to the BioNTech Vaccine, which is the one being made available. Indeed, even Pfizer acknowledges that the two vaccines are "legally distinct," and a federal court has concluded that the Comirnaty and BioNTech vaccines are not interchangeable "as a matter of law." *Austin*, 2021 WL 5816632, at *6, (N.D. Fl. Nov. 12, 2021) (concluding that BioNTech vaccines "remain 'product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.'") (Quoting 10 U.S.C. § 1107a(a)(1)).

173. The two Pfizer vaccines are legally distinct and appear to include differences. For example, the two vaccines contain a different number of ingredients: Comirnaty has eleven (11) ingredients while Pfizer-BioNTech has just ten (10) ingredients. FDA, Vaccine Information Fact Sheet for Recipients and Caregivers about COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) (Aug. 23, 2021), available at https://www.fda.gov/media/151733/download (last visited Jan. 3, 2021).

174. The approval announcement posted on the FDA's website reads, "On August 23, 2021, the FDA approved the first COVID-19 vaccine. The vaccine has been known as the PfizerBioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older." *Id.*

175. While Pfizer's Comirnaty approval letter states that its two vaccines are formulaically the same, the FDA concedes that "the products are legally distinct with certain differences …." *Id.* (emphasis added).

176. To date, no entity has revealed, nor have Plaintiffs been able to obtain, any evidence indicating what those "certain differences" may be. Despite this, the FDA inaccurately asserts that the two vaccines can be used interchangeably.

177. For example, the FDA's fact sheet for recipients and caregivers reads, "The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series." *Id.*

178. In a press release announcing Pfizer's collaboration with Brazil's Eurofarma to manufacture COVID-19 vaccine doses, Pfizer wrote, "COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech" and "PfizerBioNTech COVID-19 Vaccine has received EUA from FDA." The press release continued, stating, "This emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) …" Pfizer and BioNTech Announce Collaboration with Brazil's Eurofarma to Manufacture COVID-19 Vaccine Doses for Latin America (Aug. 26, 2021), available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-brazils (last visited Jan. 3, 2022).

179. Then, in a September 6, 2021, press release announcing a submittal to a request by the European Medicines Agency (EMA) to update its Conditional Marketing Authorization (CMA) for a booster dose, BioNTech–Pfizer's co-partner in the production of the Pfizer-BioNTech COVID-19 vaccine–clearly states, "The Pfizer-BioNTech COVID-19 vaccine has not been approved or licensed by [FDA]" but has been authorized under an EUA. Press Release, Pfizer and BioNTech Submit a Variation to EMA with the Data in Support of a Booster Dose of

COMIRNATY®, BIONTECH (Sept. 6, 2021), available at https://investors.biontech.de/node/10581/pdf (last visited Jan. 3, 2022).

180. The claim that the two vaccines are interchangeable comes from a Guidance document, which does not carry force of law. *See Christensen v. Harris County*, 529 U.S. 576, 587-88 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant Chevron-style deference."); *Appalachian Power v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (guidance documents that agencies treat as de facto law are void because they did not run the notice-and-comment gauntlet) (setting aside an agency guidance document in its entirety).

181. The FDA cannot convert a legally distinct product that is available (the BioNTech vaccine) into a fully approved vaccine (Comirnaty) that is not yet widely available. The FDA, via a mere guidance document, is attempting to establish equivalence between what are two legally distinct vaccines. That is improper as a general matter of administrative law. It is yet more improper since it is a maneuver designed to override federal statutory rights to informed medical consent and to refuse EUA products.

182. And it was recognized by a federal court in *Doe v. Austin*, which explained that even medical products FDA claims are interchangeable can contain different inactive ingredients that impact safety and effectiveness. 2021 WL 5816632, at *3 fn. 5 (citing *United States v. Generix Drug Corp*., 460 U.S. 453, 454-55 (1983)).

183. Defendants cannot be permitted to rely on mere FDA-issued guidance documents, especially where doing so would vitiate clear statutory rights.

184. Moreover, specifically referring to the Comirnaty Vaccine, Pfizer has admitted that there "is not sufficient approved vaccine available for distribution to this population in its entirety at the time of the reissuance of this EUA."

185. The Comirnaty Vaccine, the only fully FDA-approved vaccine, is not widely available and certainly is not available to all members of the population. Indeed, the Task Force Guidance fails to even list Comirnaty as an option to satisfy the Federal Contractor Vaccine Mandate. Task Force Guidance at 4. Accordingly, the EUA statute's sphere of operation continues to apply to override the Federal Contractor Vaccine Mandate.

186. Furthermore, the Federal Contractor Vaccine Mandate accepts many vaccines that have not received full FDA approval, particularly clearly less effective foreign vaccines.

Count VII: The Federal Contractor Vaccine Mandate Is Arbitrary & Capricious Under the Administrative Procedure Act ("APA")

187. Plaintiffs reallege and incorporate by reference all the foregoing allegations as though fully set forth herein.

188. Pursuant to the Administrative Procedure Act, agency action that is "arbitrary [or] capricious" is unlawful and must be set aside by a court of competent jurisdiction. 5 U.S.C. § 706(2)(A). It is arbitrary and capricious for an agency to ignore an important aspect of the problem a regulation is designed to address. *See Motor Vehicle Mfrs. Ass'n of U.S. Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action is arbitrary and capricious if the agency (i) "has relied on factors which Congress has not intended it to consider"; (ii) "entirely failed to consider an important aspect of the problem"; (iii) "offered an explanation for its decision that runs counter to the evidence before the agency"; or (iv) "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

189. Defendant's conclusion—set forth in the OMB's Revised Determination—that the Task Force Guidance's one-size-fits-all solution to reduce the cost of COVID-related absenteeism to federal contractors is economically (as well as scientifically and medically) illiterate, and therefore arbitrary and capricious. Individual federal contracting companies have stronger incentives to reduce their own net costs—including costs related to absenteeism and worker separation—than the federal government. They also have superior access to information than the federal government about their own workers' circumstances and preferences. As such, individual companies are better equipped to make tradeoffs between the need to reduce COVID-related absenteeism, on one hand, and policies regarding which of their workers should vaccinate, on the other, to manage net costs.

190. OMB's Revised Determination did not acknowledge, much less consider, the fact that numerous associations and companies warned Defendants that the Federal Contractor Vaccine Mandate would cause severe workforce and transportation disruptions—with some companies stating that they prefer to terminate federal contracts rather than comply with the costs of the mandate. *See supra* ¶ 83. These warnings contradict the Revised Determination's unsupported assertion that worker separation in response to the Federal Contractor Vaccine Mandate would be minimal. Additionally, Defendants apparently took these warnings seriously because they responded by delaying the implementation of the vaccination deadline. *See supra* ¶ 84. Yet, the Revised Determination did not mention these warnings or Defendants' response thereto.

191. OMB's Revised Determination approving the Task Force Guidance is also irrational in that it fails to explain the need to vaccinate workers who work remotely. According to the Determination, "[t]he primary goal of the safety protocols is to reduce the spread of COVID-19 among contractor employees." *Id.* at 63,421. But workers who work full-time at home or at a

remote location cannot spread to COVID-19 to fellow contractor employees. Nor can they be infected by fellow employees.

192. Similarly, Defendants offer no explanation as to why naturally acquired immunity is not a permissible ground for contractor employees to refuse to take a COVID-19 vaccine in order to keep their jobs. Evidence before the agency indicates that naturally acquired immunity exists for individuals at a level equivalent to or superior to the approved COVID-19 vaccines (e.g., one of the mandate's approved foreign vaccines with low efficacy). Failure to explain why naturally immune employees of contractor are required to take these vaccines is fatal to the policy of the Federal Contractor Vaccine Mandate. *See State Farm*, 463 U.S. at 43.

193. No less than current Pfizer Board Member and former FDA Commissioner Dr. Scott Gottlieb has acknowledged that natural immunity is an important part of the solution related to fashioning a proper public policy to address COVID-19. "It's fair to conclude …" "[t]he balance of the evidence demonstrates that natural immunity confers a durable protection." Gottlieb Interview, Squawkbox CNBC (Aug. 30, 2021) available at https://twitter.com/i/status/1432321613467357187 (last visited Jan. 3, 2022) (on the video, Dr. Gottlieb calls natural immunity not just "durable" but "robust"). Most importantly, Dr. Gottlieb told CNBC that it cannot be disputed that officials "should start assimilating [natural immunity] into our policy discussions." *Id.* Yet there is no evidence that the Task Force, OMB, or any other Defendant assimilated naturally acquired immunity into the Federal Contractor Vaccine Mandate discussion, which renders it arbitrary and capricious within the meaning of the APA, 5 U.S.C. § 706(2)(A).

194. Additional arbitrariness issues abound. For example, there is no indication that Congress intended to allow a policy like the Federal Contractor Vaccine Mandate to authorize compliance via foreign vaccines that have not been approved by duly appointed regulatory

authorities at the FDA. Indeed, it is inherently arbitrary and capricious to include on a menu of coercive vaccine options vaccines unapproved for use in the United States.

195. Furthermore, the fact that there is no ability, under any set of conditions, to apply for an exemption to the mandate even if one can demonstrate robust and durable natural immunity reveals that the Federal Contractor Vaccine Mandate rests on reasoning so implausible that it cannot be ascribed to a valid difference in expert opinion or to special agency expertise.

196. Administrative ease, the most generous explanation for the mandate's failure to recognize naturally acquired immunity, does not override an individual's right to decline an unnecessary medical intervention.

197. The APA, 5 U.S.C. § 706(2)(B), also provides a cause of action for Counts I through V pleaded above because those counts are designed to seek enforcement of the Constitution. And 5 U.S.C. § 706(2) (A)&(C) supports Count VI, which seeks invalidation of the Federal Contractor Vaccine Mandate because it is not "otherwise in accordance with law" and is "in excess of statutory jurisdiction, authority, or limitations, [and] short of statutory right."

198. Plaintiffs have suffered and will continue to suffer harm from Defendants' conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiffs or all Class Members for the deprivation of their constitutional and statutory rights, nor for the consequences of being forced to take a vaccine approved solely for emergency use. Once taken, a vaccine cannot be untaken, so Plaintiffs will suffer irreparable harm unless this Court enjoins Defendants from enforcing the Federal Contractor Vaccine Mandate.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that the Court find the Defendants have committed the violations alleged and described above, and issue in response the following:

A. A declaratory judgment that the Federal Contractor Vaccine Mandate is an exercise of legislative powers by the executive branch, in violation of Article I's Vesting Clause and of Plaintiffs' right to be governed under laws enacted by their elected representatives.

B. A declaratory judgment that the Federal Contractor Vaccine Mandate exceeds the scope of delegation under the Procurement Act to ensure an "economical and efficient system" of procurement, which requires "full and open competition" under the CICA.

C. In the alternative a declaratory judgment that the Federal Contractor Vaccine Mandate violates the non-delegation doctrine for providing no limiting or even discernible principle or direction as to the power it confers.

D. A declaratory judgment that the Federal Contractor Vaccine Mandate infringes upon Plaintiffs' constitutionally protected rights to control their bodily integrity and autonomy and to refuse unnecessary medical treatment.

E. A declaratory judgment that the Federal Contractor Vaccine Mandate represents an unconstitutional condition, especially in light of a set of explicit and implicit procedures that violate the Due Process Clause of the Fifth Amendment.

F. A declaratory judgment that the Federal Contractor Vaccine Mandate deprives Plaintiffs of their constitutional rights to pursue a career and to refuse an EUA-approved vaccine without due process of law.

G. A declaratory judgment that the Federal Contractor Vaccine Mandate represents a violation of the equal protection rights of naturally immune Plaintiffs.

H. A declaratory judgment that the Federal Contractor Vaccine Mandate is invalid under the EUA statute because it fails to provide for the informed-consent right to refuse a COVID-19 vaccine.

I. A declaratory judgment holding that the Federal Contractor Vaccine Mandate is arbitrary and capricious.

J. Temporary, preliminary, and permanent injunctive relief restraining and enjoining Defendants, their agents, servants, employees, attorneys, and all persons in active concert or participation with them (*see* Fed. R. Civ. P. 65(d)(2)), and each of them, from implementing coercive or otherwise pressuring policies, tactics, or conditions to get a COVID-19 vaccine similar to those in the Federal Contractor Vaccine Mandate; AND

K. Plaintiffs seek nominal damages of $1.

JURY DEMAND

Plaintiffs herein demand a trial by jury of any triable issues in the present matter.

January 4, 2022

Respectfully submitted,

/s/ Sheng Li
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